UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,644	09/18/2001	Eric Silverberg	1893	1184

7590 07/21/2003

Cynthia L. Foulke
NATIONAL STARCH AND CHEMICAL COMPANY
10 Finderne Avenue
Bridgewater, NJ 08807-0500

EXAMINER
GHALI, ISIS A D

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 07/21/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/955,644	SILVERBERG ET AL.	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears n the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 April 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The receipt is acknowledged of applicants' request for extension of time and amendment A, both filed 04/23/2003.

Claims 1-14 are pending.

The Standing Rejections:

(1) Double Patenting

Claims 1-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim1-17 of U.S. Patent No. 6,077,527. Although the conflicting claims are not identical, they are not patentably distinct from each other because both of the instant application and the issued patent claim an adhesive composition comprising alkyl acrylate monomer and/or alkyl methacrylate monomer and nitrogen containing monomer.

(2) Claim Rejections - 35 USC § 103

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of PGPUB '613, US '760 or US '527.

PGPUB '613 disclosed a transdermal drug delivery device comprising backing layer, release liner, and adhesive layer comprising the drug (abstract; page 2, 0018;

page 10, 0079). The adhesive comprises: (a) 40-90% by weight of alkyl acrylate including n-butyl acrylate and 2-ethylhexyl acrylate, and (b) 15-30% by weight of monomer selected from (meth)acrylamide, N-butyl-acrylamide, or (meth)acrylonitrile (page 3, 0024, 0027; page 5, 0039, 0045; page 6, 0046). The Tg is inherent for particular composition.

US '760 disclosed a transdermal drug delivery device including an adhesive layer contains active agent; backing layer, and release liner (abstract; col.5, lines 17-19, 41). The adhesive layer comprises copolymer of: (a) 45-95% by weight of alkyl acrylate including n-butyl acrylate and 2-ethylhexyl acrylate, and methacrylate, and (b) 5-55% by weight of substituted acrylamide, acrylonitrile, methacrylonitrile, and vinyl acetamide (col.2, lines 54-65; col.3, lines 1-28). The Tg is inherent for particular composition.

US '527 disclosed a pressure sensitive adhesive composition for use in transdermal drug delivery devices comprising at least 40% by weight of alkyl acrylate including n-butyl and 2-ethylhexyl acrylate, and 10-60% by weight of substituted acrylamide or methacrylamide including t-octyl acrylamide (abstract; col.2, lines 45-60; col.3, lines 60-67; col.4, lines 8-16). The Tg is inherent for particular composition.

However, BGPUB '613 and US '760 do not teach the species of the acrylamide, i.e. t-octyl acrylamide, and US '527 does not teach the backing layer and the release liner of the transdermal device.

It is within the skill in the art to replace one species by another or genus by species known to perform the same function. Thus, it is obvious to replace the

substituted acrylamide of any of PGPUB '613 or US '760 by t-octyl acrylamide. In any event, no criticality has been shown in using t-octyl acrylamide in particular.

It is also within the skill in the art to deliver a conventional transdermal drug delivery device comprising backing layer and release liner enclosing the adhesive layer containing the drug.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver a transdermal drug delivery devices comprising a backing layer, a release liner and an adhesive composition comprising alkyl acrylate and substituted (meth)acrylamide and select the species suitable for the adhesive layer with reasonable expectation of the device to deliver therapeutically active agents transdermally with success.

Applicants' Arguments:

- US '527 does not disclose adhesive composition that lacks functional groups containing reactive hydrogen moieties and contains no post-polymerization chemical crosslinker. The reference disclosed the use of acrylic acid and vinyl monomer that contains functional groups and the use of crosslinker is required. The reference is concerned with the problem associated with the use of penetration enhancer in the adhesive while the present invention is concerned with problems associated with reactivity of the drug with adhesives.

- PGPUB '613 concerned with adhesive for use with highly plasticizing drugs and contains functionalizing monomer, which facilitates crosslinking and may contain crosslinking agent.
- US '760 teaches acrylic acid and hydroxylalkyl acrylate that cannot be used in the present invention.
- Nothing in the references' disclosure that would motivate the skilled artisan to select the components for use in the practice of applicants' claimed invention.

Examiner's Position:

- The adhesive composition disclosed by US '527 is the same as applicants, and referring to the structural formulae in col.2 and 3 of the reference, no reactive hydrogen moieties are present, which are –COOH, OH and $–NH_2$, which are disclosed by applicants as reactive hydrogen moieties at page 5 of the present specification. Further the formulae are identical to the formulae on page 6 of the present specification. Thus, no reactive hydrogen moieties are disclosed by US '527 except for the optional ingredient (iv) disclosed in col.4, lines 17-19. The use of the crosslinker is also an optional and not a requirement, col.3, lines 20-25; col.4, lines 18-20, and that means the composition can exist without any of the reactive hydrogen moieties or the crosslinker. In applicants' specification at page 5, lines 10-13, applicants state that the "No post-polymerization chemical cross-linking means that while monomers having multiple polymerization sites may be use to prepare the adhesive of the invention, following polymerization no reactive

sites are present in the polymer". Thus, applicants' disclosure and claims do not exclude the presence of the cross-linker itself, but the reactive sites after polymerization (cross-linking), and the formulae disclosed by the reference are free from reactive sites. Further, the "comprising" language of the claims permits the presence of other ingredients such as functionalizing polymers and crosslinker. No superior and unexpected results of record to show the criticality in the adhesive composition lacks functional groups containing reactive hydrogen moieties and contains no post-polymerization chemical crosslinker. The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain. *In re Heck*, 699 F.2d 1331, 1332—33, 216 USPQ 1038, 1039 (Fed. Cir 1983). The present claims are directed to composition, and all the elements of the composition are disclosed by the reference. For the above reasons, the examiner believes that the double patenting is proper because the reference claims the same claimed adhesive composition.

- The present claims are directed to composition, and all the elements of the composition are disclosed by PBPUB '613. The expression "comprising " permits the presence of other ingredients and does not preclude the presence of other ingredients, active or inactive, even in major amounts. Thus, the claim language permits the presence of functional monomers and crosslinker for the same or

other function in the composition, not for adhesive properties. See *Moleculon Research Corporation v CBS, Inc.* 229 USPQ 805, *In re Baxter* 210 USPQ 795, 803. No superior and unexpected results of record to show the criticality in the adhesive composition lacks functional groups containing reactive hydrogen moieties and contains no post-polymerization chemical crosslinker. The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain. *In re Heck*, 699 F.2d 1331, 1332—33, 216 USPQ 1038, 1039 (Fed. Cir 1983). A reference may be relied upon for all that it would have reasonable suggested to one having ordinary skill in the art.

- US '760 disclosed composition comprising copolymer of: (a) 45-95% by weight of alkyl acrylate including n-butyl acrylate and 2-ethylhexyl acrylate, and methacrylate, and (b) 5-55% by weight of substituted acrylamide, acrylonitrile, methacrylonitrile, and vinyl acetamide . The comprising language of the claim permits the presence of acrylic acid and hydroxylalkyl acrylate in the composition. No superior and unexpected results of record to show the criticality in the adhesive composition lacks functional groups containing reactive hydrogen moieties and contains no post-polymerization chemical crosslinker. The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the

literature of the art, relevant for all they contain. *In re Heck*, 699 F.2d 1331, 1332—33, 216 USPQ 1038, 1039 (Fed. Cir 1983). A reference may be relied upon for all that it would have reasonable suggested to one having ordinary skill in the art.

- In response to applicant's argument that there is no motivation in the references to select the components required to practice the present invention, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver a transdermal drug delivery devices comprising a backing layer, a release liner and an adhesive composition comprising alkyl acrylate and substituted (meth)acrylamide and select the species suitable for the adhesive layer with reasonable expectation of the device to deliver therapeutically active agents transdermally with success. No superior and unexpected results of record to show the criticality in the adhesive composition lacks functional groups containing reactive hydrogen moieties and contains no post-polymerization chemical crosslinker.

1. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6,239,228 disclosed transdermal drug delivery device comprising adhesive layer comprising alkyl acrylate and substituted acrylamide.

Conclusion

2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (703) 305-4048. The examiner can normally be reached on Monday through Thursday from 7:00 AM to 5:30 PM, Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

Isis Ghali
Examiner
Art Unit 1615

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600